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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,100	12/02/2003	Francesco Di Salvo	DI SALVO	9233

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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,100

Applicant(s)

SALVO, FRANCESCO DI

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-47 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25 and 30-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The application is published application number: 2004/0236203.

The Applicant is requested to provide at the beginning of the Specification all updated status (serial numbers and patent numbers) of related applications.

Amendment filed 11-7-05.

Pending claims are 20-47. Claims 26-29 are withdrawn. Claims 20-25 and 30-47 are addressed, *infra*.

This action is final. The prior **35 USC § 102** rejection is changed to a **35 USC § 103** rejection in response to the amendments dated 11-7-05. The Applicant's amendments addressed the issue of anticipation by Schmid (4,375,219), but did not evade the obviousness issues that still exist. As such, all remaining rejections are under **35 USC § 103**. (The erstwhile rejection under **35 USC § 112** is obviated.)

Claim Rejections - 35 USC § 112

Claim 20-25 and 30-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification does not include the germanium range now disclosed. The originally claimed germanium range 0.01% to 20% is a "genus". The now claimed 0.01% to 3% is a subgenus. According to MPEP

2163 under the Written Description Requirement (see *B. New or Amended Claims*), the Applicant cannot amend claims, which introduce limitations not supported by the original disclosure. The courts hold (*In re Lukach*) that a subgenus range (such as 0.01% to 3%) is not necessarily described by a genus (0.01% to 20%) encompassing it and a species upon which it reads. In addition, the Specification makes no mention as to criticality of the newly amended range appearing to be inserted into the claim merely to circumvent the current rejection. Therefore, the amended claims include new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 23-25, 30-34, 36-40, 43-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid (4,375,219).

Schmid neglects to expressly disclose parameters and dimensions (for alloy weight ratios, hardness and conductivity), however the Applicant's claimed parameters and dimensions would have been obvious as a result of routine experimentation with the Schmid electrode. The motivation to perform the experimentation would be to determine optimal parameters and dimensions (which are presumably claimed by the Applicant).

Note: Re: 43, 45. Schmid's structurally equivalent electrode makes obvious an alloy capable of emitting anions, as well as resistance to corrosion.

Schmid discloses a silver germanium alloy electrode (see preferred compositions for the medical electrodes atop column 7). Silicon is also mentioned (col. 7:24).

Dependent claims (parentheticals refer to Schmid).

23. The instrument of claim 20, wherein medical instruments include devices selected from the group of prostheses and implants of suitable shape and size. (The office contends that Schmid electrodes are capable of implantation.)

24. The instrument of claim 20, capable of emitting far infrared radiation upon contact with a biological tissue and which is capable of entering into molecular resonance vibration with bio structure and physical structures of so irradiated biological tissue.

25. The instrument of claim 20, capable of creating an ohmic contact in an electrode-tissue interface (the electrodes attach to skin) during electrosurgical operative modes.

31. The instrument of claim 20, wherein the germanium content is less than 14.4% by weight. See col. 7, example I.

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32. The instrument of claim 31. wherein the germanium content is at least 0.01% by weight. See col. 7, example I.

(36 and 37 are again discussed in the Response to Arguments section.)

36. The instrument of claim 20, wherein the non-hydrogenic and the hydrogenic acceptor dopants are selected from the group consisting at least one of gold, platinum, copper (see col. 7:4-5), gallium, indium, zinc, boron and their alloys.

37. The instrument of claim 36, wherein the non-hydrogenic acceptor dopant is at least one of gold and copper (see col. 7:4-5).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid in view of Robichaud (3,752,151).

Schmid neglects to disclose laminate.

In an analogous electrode, Robichaud discloses laminate (see title). Therefore it would have been obvious at the time of the invention to modify Schmid in view of Robichaud by including laminate as a design expedient. The motivation would be to use a well-known means (laminate) to package a silver alloy for use as an electrode.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid in view of Ueda et al. (3,816,293).

Schmid neglects to disclose fusion.

In an analogous electrode, Ueda et al. discloses fusion (col. 4:1-5). Therefore it would have been obvious at the time of the invention to modify Schmid in view of Ueda by including fusion as a production method. The motivation would be to use a well-known production method ("conventional").

Claims 35 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid in view of Kiyama et al. (4,668,840).

Schmid neglects to disclose microcrystals.

In an analogous electrode, Kiyama et al. discloses microcrystals (col. 1:24-30) in the claimed context. Therefore it would have been obvious at the time of the invention to modify Schmid in view of Kiyama by including microcrystals as a design expedient. The motivation would be to use a well-known alloy configuration to permit its effective use as an electrode.

Note: Schmid discloses energy emitting electrodes obviously capable of emitting RF and thermal energy (by definition of electrode).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmid in view of Popp et al. (5,822,177).

Schmid neglects to disclose fractal surfaces.

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In an analogous electrode, Kiyama et al. discloses fractal surfaces (see title) in the claimed context. Therefore it would have been obvious at the time of the invention to modify Schmid in view of Popp by including fractal surfaces as a design expedient. The motivation would be to use a well-known alloy configuration to permit its effective use as an electrode.

Response to Arguments

Applicant's arguments with respect to claims 20-25 and 30-37 have been considered but are moot in view of the new ground(s) of rejection. As mentioned above, the amendments dated 11-7-05 address anticipation, but not obviousness. Although the newly amended constituent ranges are not expressly disclosed by Schmid, the patent does disclose constituent ranges that are sufficiently similar (Schmid discloses 5% germanium in "Example I" whereas the Applicant **attempts** to disclose 3% germanium **(more specifically 1.83% in ¶ [0065], [0066] [0068].)** to warrant a rejection based upon obviousness. In other words, the office contends that one of ordinary skill in the art would have viewed Schmid (and the other art presented above) and through routine experimentation determined the Applicant's claimed invention. The Applicant's approach in the claim language is to broadly and alternately ("by one or more of") claim many materials of varying ranges. This approach makes the claims widely susceptible to obviousness rejections (as there are so many combinations that could be construed by the Examiner in viewing the claims). **Further, the Application neglects to disclose**

criticality of the newly claimed percentages or unexpected results that might arise from the newly claimed percentages (Also, see arguments toward new matter in the above 35 USC § 112 rejection). To this end, the claims are still rejected.

Also, the 11-3-05 amendment introduced the term, "between" into the independent claims (20 and 30) requiring that a "dopant" be included in the claim apprehension. This has no effect on the rejections, as the Office still contends that Schmid makes obvious all constituents and their percentages claimed by the Applicant (germanium, a dopant – ex. gold, copper, and additional compounds – ex. silicon). See the underlined portions of the rejections above (toward claims 36-37). Also, see the four examples in the Schmid patent, which collectively include germanium, silicon, copper and gold.

The Applicant argues that Schmid does not mention implantation. However, this claim language (found in claim 23) is toward the intended use of the invention, which carries little patentable weight in an instrument claim. (Instrument structure, and not use, is the main focus when examining instrument/apparatus claims.)

The Applicant argues that Schmid is not analogous art. The Office respectfully disagrees. Both Schmid and the claimed invention are **electrodes**, which in the medical field are used for many purposes including those for diagnosis (Schmid) and therapy (Applicant). The nexus between the two are so close that certain medical devices

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include electrodes that serve dual roles of diagnosis and therapy (ex. ablation) such as the mapping catheter in USPN (6,099,524 – see *BRIEF DESCRIPTION OF DRAWINGS Fig. 4*). As, such the Office contends that diagnostic electrodes and therapeutic electrodes are indeed from analogous arts and the rejections above to this regard are valid.

It is further noted that the Applicant repeatedly argues against the combination of the patents above used to reject **dependent** claims. All of the arguments presuppose too much importance towards the intended uses of the patented inventions. These arguments would be more potent toward method claims (intended use is very important), or if the related dependent claims were introduced into the independent claims and collectively a potentially effective argument could be made against combining several of the patents into one obviousness rejection. (This is proffered with the intent to help the Applicant.)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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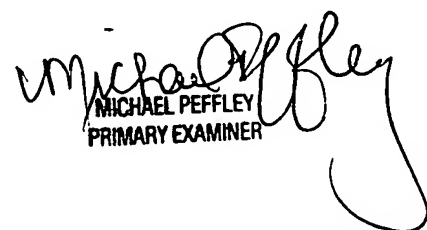
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
January 14, 2006



MICHAEL PEFFLEY
PRIMARY EXAMINER